

## Remarks

This is in response to the non-final Office Action mailed October 10, 2006. Claims 1-17 remain pending. Claims 1-17 are amended with support found throughout the specification. With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter. No new matter is added. Reconsideration and allowance are requested for the following reasons.

### **Claim Objections**

Claims 3 and 11 are objected to for misspelling of Schamberg's disease. Correction has been made.

### **35 U.S.C. § 101 and 35 U.S.C. § 112**

Claims 1-10 are rejected for being non-statutory "use" claims. Claims 1-10 are amended into method claim format. No new matter is added. Withdrawal of the rejections is requested.

### **35 U.S.C. § 103**

Claims 1-17 are rejected as being unpatentable over Elson (WO 97/39746) in view of Elson (US Patent 5,510,391), further in view of Crandall (US Patent 5,945,409). Applicants respectfully traverse the rejection.

In order to establish a prima facie case of obviousness, three basic criteria must be met, namely: 1) the references when combined must teach or suggest all of the claim limitations; 2) a suggestion or motivation to modify the references or combine the reference teachings must be present; and 3) the references when combined must provide a reasonable expectation of success. Applicants submit that all of these requirements have not been met.

Independent claim 11 is directed to a composition including a compound of formula I, which includes for example vitamin K1 oxide, and phospholipids, ethoxy diglycol, and a cosmetic carrier. Independent claim 1 is a method of treating or preventing dermatological lesions using a composition including a compound of formula I, e.g., vitamin K1 oxide.

In contrast, Elson (WO) teaches treatment of skin conditions by application of a vitamin K1 cream. The Office has admitted that the Elson (WO) reference does not teach use of vitamin

K1 oxides, such as those of formula 1. Contrary to the assertions of the Office, ‘391 patent also does **not** teach use of vitamin K1 oxides.

The language relied upon by the Office in the ‘391 patent is found only in claims 5 and 8.

5. The method of treating blood vessel disorders of the skin and skin disorders caused by photoaging as in claim 1, wherein the form of vitamin K used in said pharmaceutical composition is selected from the group consisting of vitamin K-1, vitamin K-2 and synthetic vitamin K analogs.

The only teaching in the ‘391 patent which describes what compounds are considered “synthetic vitamin K analogs” is found at Col. 1, lines 32-39, reproduced below:

In addition, vitamin K analogs have been synthesized and currently include vitamins K-3, K-4, K-5, K-6 and K-7.

The teaching of the ‘391 patent is limited to vitamins K-1, K-2, K-3, K-4, K-5, K-6 and K-7. Consequently, neither the Elson (WO) and the Elson (‘391) references teach vitamin K-1 derivatives, such as vitamin K-1 oxide, or its effectiveness or use for treating dermatological lesions. The claimed vitamin K-1 oxide compounds of formula I and their use for treating dermatological lesions was not taught or suggested by the combination of Elson (WO) and Elson ‘391.

The Crandall reference makes no specific teachings or suggestions for use of vitamin K-1 oxides for treating or preventing dermatological lesions. Therefore, Crandall does not rectify the deficiencies of Elson (WO) and Elson (‘391).

In addition, the combination of Elson (WO) and Elson (‘391) fails to teach the use of ethoxy diglycol in a composition containing vitamin K-1 (or vitamin K-1 oxides). While Crandall makes general teachings regarding carriers, Crandall does not teach selection of ethoxy diglycol for use with vitamin K-1 oxide.

Furthermore, compositions and methods of treating or preventing dermatological lesions using vitamin K-1 oxide presents several surprising advantages over compositions including vitamin K-1. Compositions including vitamin K-1 oxide have been shown increased effectiveness in treatment of bruises and spider veins as compared to similar vitamin K-1 creams.

In addition, a vitamin K-1 oxide composition of the present invention was compared side-by-side with a vitamin K-1 cream for prevention and treatment of bruising in patients undergoing eyelid surgery. The “Auriderm XO gel” which includes vitamin K-1 oxide prevented significant bruising compared to the vitamin K composition (Auriderm K2 gel). Please see Declaration of Dr. Karavani accompanying this Response.

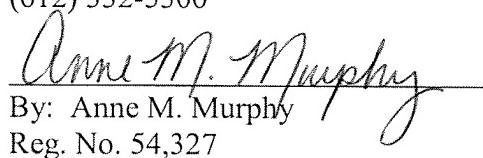
In addition, Vitamin K-1 oxide, in contrast to vitamin K-1, does not transform into by-products in the presence of light potentially leading to side effects of treatment, such as allergic reaction to the creams or gels during use.<sup>1</sup> Also, the inventive composition including vitamin K-1 oxide has increased stability and does not present the yellow color of vitamin K-1 creams and other vehicles in use and therefore does not stain the clothes of the person using the composition.

For at least the above reasons, the methods of independent claim 1 and the vitamin K-1 oxide composition of independent claim 11 are believed to be patentable in view of Elson (WO), Elson ('391) and Crandall. Claims 2-10 and 12-17 are dependent from independent claims 1 and 11, therefore the same constraints and reasoning apply.

Favorable reconsideration in the form of a Notice of Allowance is requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted. Please contact the undersigned with any questions regarding this application.

Respectfully submitted,  
MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

Date: April 10, 2007

  
By: Anne M. Murphy  
Reg. No. 54,327

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<sup>1</sup> Application, page 10, lines 11-21